

Attorney Docket No.: ISPH-0569  
Inventors: Anderson et al.  
Serial No.: 09/853,409  
Filing Date: May 11, 2001  
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#### REMARKS

Claims 1-24 are pending in the instant application. Claims 1-22 have been withdrawn from consideration. Claims 23 and 24 have been rejected. Claims 1-22 have been canceled. Claims 23 and 24 have been amended. New claims 25 and 26 have been added to further clarify the methods of the instant invention. No new matter has been added by these additions and amendments to the claims. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### I. Restriction/Election

The Restriction Requirement placing claims 1-8 into Group I, claims 9-14, 19 and 20 into Group II, claims 15-18, 21 and 22 into Group III, and claims 23 and 24 into Group IV has been deemed proper and made final. Accordingly, Applicants have canceled without prejudice claims 1-22, reserving the right to file continuing applications on the canceled subject matter.

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## II. Rejection of Claims Under 35 U.S.C. 102(e)

Claims 23 and 24 have been rejected under 35 U.S.C. 102(e) as being anticipated by Cho-Chung (US Patent 5,627,158). The Examiner suggests that this patent discloses a composition comprising antisense oligonucleotides for subcutaneous administration and a method of inhibiting the expression of RI-alpha encoding gene in animals. Applicants respectfully traverse this rejection.

At the outset, Applicants have amended claims 23 and 24 and added new claims 25 and 26. Support for these additions and amendments to the claims can be found throughout the specification as filed but in particular at pages 31-44.

Cho-Chung et al. disclose the use of antisense compounds targeted to the RI-alpha gene and subcutaneous administration of said compounds. Nowhere does this patent teach or suggest antisense compounds as now claimed which are targeted to hepatitis C virus. In order to anticipate an invention the cited reference must teach each and every limitation of the claims (MPEP 2131). Accordingly, this reference cannot anticipate the instant invention as now claimed and withdrawal of this rejection is respectfully requested.

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Claims 23 and 24 have been rejected under 35 U.S.C. 102(c) as being anticipated by Feinberg et al. (US Patent 5,276,017). The Examiner suggests that this patent discloses antisense compounds for subcutaneous administration wherein the antisense oligonucleotide is administered to animals and inhibits gene expression of a gene encoding tropho-uteronection. Applicants respectfully traverse this rejection.

As discussed supra, Claims 23 and 24 have been amended to recite compositions and methods specific for inhibition of hepatitis C virus expression in animals. As acknowledged by the Examiner, the patent of Feinberg et al. discloses only antisense compounds targeted to tropho-uteronection. Nowhere does this patent teach or suggest antisense compounds as now claimed which are targeted to hepatitis C virus. In order to anticipate an invention the cited reference must teach each and every limitation of the claims (MPEP 2131). Accordingly, this reference cannot anticipate the instant invention as now claimed and withdrawal of this rejection is respectfully requested.

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### III. Rejection of Claims Under 35 U.S.C. 112, First Paragraph

Claims 23 and 24 have been rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The Examiner suggests that specification and claims as originally filed do not provide support for the broad scope of the claimed subject matter. Applicants respectfully traverse this rejection.

As discussed supra, the claims have been amended to recite compositions and methods associated with inhibition of expression of hepatitis C virus. Support for these amendments can be found at pages 35-44 of the specification as filed. At these pages, the specification as filed teaches antisense compounds targeted to hepatitis C virus, methods for inhibiting hepatitis C virus expression using said antisense, methods for treating an animal infected with hepatitis C virus, as well as methods for inhibiting replication of the virus. Data are provided showing in vivo activity of the compounds of the instant invention after subcutaneous injection. Accordingly the claims as amended meet the

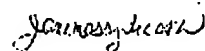
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requirements of 35 U.S.C. 112, first paragraph. Withdrawal of this rejection is respectfully requested.

#### IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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